# Document made available under the Patent Cooperation Treaty (PCT)

International application number: PCT/US05/005813

International filing date: 25 February 2005 (25.02.2005)

Document type: Certified copy of priority document

Document details: Country/Office: US

Number: 60/547,748

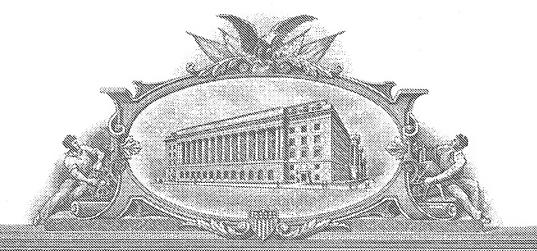
Filing date: 25 February 2004 (25.02.2004)

Date of receipt at the International Bureau: 06 May 2005 (06.05.2005)

Remark: Priority document submitted or transmitted to the International Bureau in

compliance with Rule 17.1(a) or (b)





## 

TO AND TO THE SERIES ENTRY SHAME (CONTRO)

#### UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

April 25, 2005

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A FILING DATE.

APPLICATION NUMBER: 60/547,748 FILING DATE: February 25, 2004

RELATED PCT APPLICATION NUMBER: PCT/US05/05813

1313531

Certified by

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office Approved for use through 07/31/2006. OMB 0651-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filling a PROVISIONAL APPLICATION FOR PATENT.

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No. EU825077767US

INVENTOR(S)						
Given Name (first and middle [if any]) Family Name or Surname			Residence (City and either State or Foreign Country)			
David C.	Amundson		Boulder,			
Additional inventors are being named on thesep			ately numbered sheets attached hereto			
TITLE OF THE INVENTION (500 characte						
Coronary Sinus Locater Sheath for Biventricular Pacing						
Direct all correspondence to: CORRESPONDENCE ADDRESS  Customer Number:					15535 60/5	
OR Firm or Part 5 Western						
Individual Name Peter F. Weinberg	Peter F. Weinberg					
Address Gibson, Dunn & Crutcher						
0.11	1801 California St., Suite 4100					
City Denver		State Telephone	CO	Zip	80202	
Country United States of Am	RTS (check al	3032985901	гах	3033132827		
Specification Number of Pages 5 Two figures are incorporated CD(s), Number CD(s), Numb						
Applicant claims small entity status. See 37 CFR 1.27.  A check or money order is enclosed to cover the filing fees. Check No. 44 756  The Director is herby authorized to charge filing fees or credit any overpayment to Deposit Account Number: 50-0792  Payment by credit card. Form PTO-2038 is attached.						
The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.  No.  Yes, the name of the U.S. Government agency and the Government contract number are:  [Page 1 of 2]						
Respectfully submitted,  SIGNATURE	i F	Date 2-25-04  REGISTRATION NO. 40866 (if appropriate) Docket Number: 03383-1-2				

TELEPHONE 3032985901

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop Provisional Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

#### Patent Disclosure

### Coronary Sinus Locater Sheath for Biventricular Pacing

#### Introduction

A rapidly growing field in cardiology is the treatment of congestive heart failure with cardiac pacing (biventricular pacing). In biventricular pacing, besides the conventional right atrial and ventricular pacing leads, an additional lead is placed in the coronary sinus and advanced through the vasculature to a position adjacent to the left ventricle. Pacing the left and right ventricles simultaneously has been found to be beneficial in these patients.

Locating the coronary sinus with a catheter is often an arduous task. The coronary sinus is a small hole about 1-2 cm in diameter, located within a few centimeters posterior to the inferior vena cava in the right atrium. Often, the coronary sinus has a small valve (thespian valve), which partly or completely covers the opening. Moreover, in congestive heart failure patients, the heart is hypertrophied, distorting the normal geometry of the heart.

Currently, the coronary sinus is cannulated by introducing a deflectable or fixed-curve sheath or catheter into the right atrium and manipulating the sheath/catheter until the cardiologist "feels" an entry into an orifice. Puffing dye and viewing the dye puff on fluoroscopy make positive verification of entry into the coronary sinus. If a catheter is used, a sheath is then placed over the catheter and the catheter withdrawn. The sheath is then advanced into a branch vein leading to the left ventricle. At this point, a guidewire can be inserted into the sheath to aid in navigation of a suitable venous branch adjacent to the left ventricle. The guidewire is floppy and can be easily manipulated to enter various branches of the coronary sinus vasculature. Once the proper branch is thought to be located, as evidenced by fluoroscopy, a pacing lead with a center lumen suitable for guidewire insertion is advanced over the guidewire to the desired location. At that point, pacing thresholds are determined, and if acceptable the lead is connected to the implanted pulse generator. If they are not acceptable, the lead or guidewire is again manipulated to find a new location. This becomes an iterative procedure until acceptable pacing thresholds are obtained.

#### Summary of Invention

Locating the Coronary Sinus

Apparatus and means are disclosed for cannulating the coronary sinus with a sheath or catheter. The sheath or catheter has a side port near the distal end where a guidewire can be advanced into the inferior vena cava. The procedure is to advance the sheath/catheter (without guidewire advancement out of the side port) into the inferior vena cava. Fluoroscopy, infrared endosocpic imaging, intracardiac echo or other means verifies placement in the inferior vena cava. Once in the inferior vena cava, the guidewire is advanced out of the side port and the sheath/catheter is retracted into the right atrium, anchored by the guidewire still residing in the inferior vena cava. Anchoring in the inferior vena cava stabilizes the sheath in a position near the coronary sinus. Small manipulations or rotation will orient the catheter/sheath near the coronary sinus. Once the coronary sinus is engaged, the guidewire is retracted from the inferior

vena cava, allowing sheath/catheter to be further advanced through the coronary sinus vasculature.

With an anchored sheath, a variety of locater catheter/guidewire technologies could be used to locate the coronary sinus. They include:

- 1. An electrophysiology catheter
- 2. A guide sheath
- 3. A guidewire
- 4. Infrared imaging catheter
- 5. An electromagnetic mapping catheter (e.g. a magnetic catheter operating with the CARTO mapping system by Biosense Webster)
- 6. an intracardiac echo catheter

After the guide sheath containing one of the above devices is routed to the desirable location adjacent to the left ventricle the following invention can be utilized:

#### Pacing Threshold Evaluation

Once the sheath is guided to the proper location in the coronary sinus vasculature, pacing thresholds as well as deleterious pacing effects such as phrenic nerve stimulation can be assessed by having two rings on the sheath mimicking pacing electrodes. These electrodes are connected by wires to outside the patient. They are connected to a pacing threshold analyzer. The analyzer is used to determine pacing threshold and phrenic nerve and muscle stimulation potential.

#### Implantation of Pacing Lead

After a site is examined for its suitability as a pacing site, the catheter is removed. A guidewire is inserted in the sheath and a coronary sinus pacing lead is inserted through the sheath over the guidewire to the distal end to the same location where successful pacing was observed. The sheath and guidewire are then removed leaving the pacing lead in a position suitable for long term pacing. After pacing threshold evaluation, the lead is then connected to the pulse generator.

#### Detailed Description of the Invention

This embodiment uses the infrared imaging catheter described in US Patent 6178346. The infrared imaging catheter is inserted in a sheath containing the guidewire port about 3-10 cm from the distal end of the sheath. The sheath also has two electrodes near the distal end. The most distal electrode is about 10 square millimeters in surface area. One centimeter back from the most distal electrode is the proximal electrode about 30 square millimeters in surface area. Both electrodes are connected to insulated wires, which extend out the proximal end of the sheath for connection to a pacing analyzer.

Using fluoroscopy or the infrared images, the catheter is guided to the inferior vena cava. Once in the inferior vena cava, the guidewire is then extended. The guidewire may be a traditional guidewire used in navigating vasculature structures or a more rigid device similar to stylets used in pacemaker leads. Once the guidewire is extended, the sheath-catheter is retracted out of the inferior vena cava with the guidewire still in place inside the inferior vena cava. The guidewire now serves as an anchor for the sheath-catheter. The sheath-catheter is then articulated and rotated until the coronary

sinus comes into view. Once in view, the sheath-catheter is advanced into the coronary sinus. Alternatively, the sheath-catheter could have a fixed curve and be rotated to find the coronary sinus. This could be accomplished several ways. The catheter may be telescoped from the sheath into the coronary sinus. Or the sheath-catheter assembly could be advanced into the coronary sinus. Once the coronary sinus has been engaged, the guidewire is withdrawn out of the inferior vena cava and the imaging catheter is used to navigate the coronary sinus vasculature. As the sheath-catheter is advanced, branches will be imaged. The sheath-catheter can be rotated or articulated to enter a particular branch.

Once the sheath-imaging catheter has reached a desirable pacing site, the wires are connected to a pacing analyzer and pacing thresholds are obtained. Phrenic nerve stimulation is evaluated by pacing at 10 volts. If suitable thresholds are found with no phrenic nerve stimulation, the imaging catheter is withdrawn. A stylet is then inserted in the sheath and routed beyond the distal end of the sheath. Over the guidewire, a coronary sinus pacing lead is inserted and advanced to the end of the sheath so that the pacing electrodes are adjacent to the electrodes on the sheath. The sheath is withdrawn and pacing thresholds are again obtained with the pacing lead. If still acceptable, the lead is connected to the pacemaker.

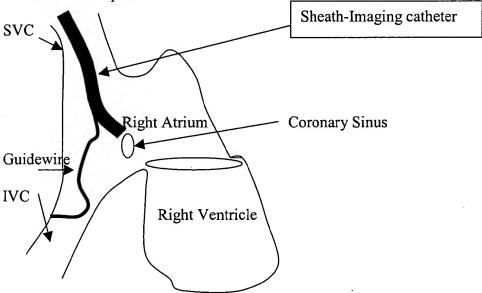


Fig 1: Imaging catheter-sheath with guidewire extending into inferior vena cava

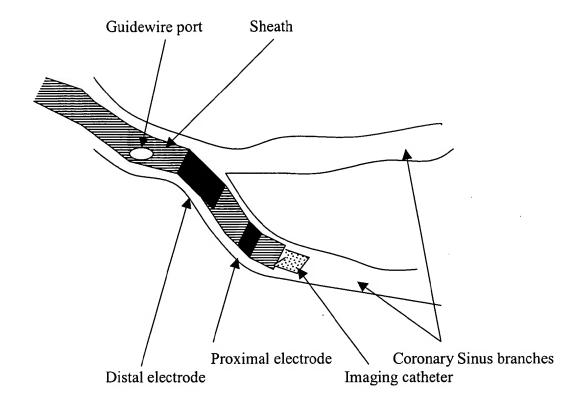


Fig 2: Sheath-imaging catheter inside coronary sinus branch

In this embodiment, an electrophysiology catheter is used. The electrophysiology catheter is inserted in a sheath containing the guidewire port about 3-10 cm from the distal end of the sheath. The sheath also has two electrodes near the distal end. The most distal electrode is about 10 square millimeters in surface area. One centimeter back from the most distal electrode is the proximal electrode about 30 square millimeters in surface area. Both electrodes are connected to insulated wires, which extend out the proximal end of the sheath for connection to a pacing analyzer.

Using fluoroscopy, the catheter is guided to the inferior vena cava. Once in the inferior vena cava, the guidewire is then extended. The guidewire may be a traditional guidewire used in navigating vasculature structures or a more rigid device similar to stylets used in pacemaker leads. Once the guidewire is extended, the sheath-catheter is retracted out of the inferior vena cava with the guidewire still in place inside the inferior vena cava. The guidewire now serves as an anchor for the sheath-catheter. The sheath-catheter is then articulated and rotated until the coronary sinus is engaged by a combination of tactile feel and fluoroscopy. Once in view, the sheath-catheter is advanced into the coronary sinus. This could be accomplished several ways. The

electrophysiology catheter may be telescoped from the sheath into the coronary sinus. Or the sheath-catheter assembly could be advanced into the coronary sinus. Once the coronary sinus has been engaged, the guidewire is withdrawn out of the inferior vena cava and the electrophysiology catheter is used to navigate the coronary sinus vasculature. As the sheath-catheter is advanced, branches will be imaged by puffing dye through the sheath and viewing the fluoroscopic image. The sheath-catheter can be rotated or articulated to enter a particular branch.

Once the sheath-electrophysiology catheter has reached a desirable pacing site, the wires are connected to a pacing analyzer and pacing thresholds are obtained. Phrenic nerve stimulation is evaluated by pacing at 10 volts. If suitable thresholds are found with no phrenic nerve stimulation, the electrophysiology catheter is withdrawn. A stylet is then inserted in the sheath and routed beyond the distal end of the sheath. Over the guidewire, a coronary sinus pacing lead is inserted and advanced to the end of the sheath so that the pacing electrodes are adjacent to the electrodes on the sheath. The sheath is withdrawn and pacing thresholds are again obtained with the pacing lead. If still acceptable, the lead is connected to the pacemaker.

In summary, this invention teaches a method of cannulating the coronary sinus with a sheath-catheter by anchoring in the inferior vena cava with an extendable member from a side port in the sheath. This places the sheath-catheter in the near vicinity of the coronary sinus. The coronary sinus is then engaged and the extendable member is then retracted to permit further advancement in the coronary sinus vasculature. Once an appropriate pacing site is found, the pacing viability can be assessed by pacing with electrodes located near the distal end of the sheath. If acceptable thresholds are obtained, the catheter is removed and replaced with a pacing lead. Finally, the sheath is retracted leaving the pacing lead in place ready for connection to the biventricular pacemaker.

Not all of the disclosed features of the present invention need to be combined in any particular embodiment, and the inventor may regard any subset of the disclosed features as patentable.